Message

From: Metzger, Michael [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=655BC1C05459419D8BB3BA9A16568C3F-MICHAEL S. METZGER]
Sent: 5/9/2019 5:22:14 PM
To: Miller, David [Miller.DavidJ@epa.gov]
Subject: RE: aldicarb and then also carbaryl and terbufos epi.

Thanks, David.

From: Miller, David
Sent: Thursday, May 09, 2019 11:05 AM
To: Swartz, Christina <Swartz.Christina@epa.gov>; Metzger, Michael <Metzger.Michael@epa.gov>; Mendez, Elizabeth <Mendez.Elizabeth@epa.gov>
Cc: Doherty, Michael <Doherty.Michael@epa.gov>; Niman, Aaron <niman.aaron@epa.gov>
Subject: aldicarb and then also carbaryl and terbufos epi.

Liz

– thanks.

Christina and Mike M. ,

Ex. 5 Deliberative Process (DP)

Mike M. –

also below is aldicarb, Aglogic, and Larry Hodges, No need for you to do anything, but you might end up being invited by RD's Marion Johnson to a meeting with Larry H. on this aldicarb topic. I suspect he will be persistent.

David.

From: Mendez, Elizabeth
Sent: Thursday, May 09, 2019 10:47 AM
To: Miller, David <Miller.DavidJ@epa.gov>
Cc: Doherty, Michael <Doherty.Michael@epa.gov>; Niman, Aaron <niman.aaron@epa.gov>
Subject: Re: Changes to compounds to be evaluated in JMPR September 2019 [SEC=UNCLASSIFIED]

David,

Ex. 5 Deliberative Process (DP)

Sent from my iPhone

On May 9, 2019, at 10:30 AM, Miller, David <Miller.DavidJ@epa.gov> wrote:

> Mike and Liz
>
> The email chain below relates specifically to aldicarb, but I note the following from WHO's Soren Madsen as ot relates to epidemiology of terbufos and carbaryl:
>
> > Dear Ian and Karina,
> >
> > It was a pleasure meeting you in Macau.
> >
> > I wish to inform you that we have had to make some changes in the JMPR schedule for the evaluation of Terbufos and Carbaryl.
> >
> > Despite several attempts, it has not been possible to find willing and able epidemiological expertise to commit to the evaluation of these two compounds for the September 2019 JMPR meeting.
> >
> > As time is drawing near, I have had to choose between an evaluation without the epidemiological component or a postponement of the evaluation to September 2020.
> >
> > We now have a senior epidemiologist who have committed to undertake the 2020 epidemiological evaluation, and I have decided to go for a complete (but postponed) evaluation rather than a less complete evaluation in accordance with the initial schedule for the September 2019 JMPR meeting.
> >
> > I suppose that you may want to reflect these changes in the CCPR spreadsheet.
> >
> > Best Regards,
> >
> > Soren Madsen
> > Department of Food Safety and Zoonoses
> > World Health Organization
> > 20, Avenue Appia, CH-1211 Geneva 27
> > Switzerland
> > Tel direct: + 41 22 791 36 97

Ex. 5 Deliberative Process (DP)

From: Miller, David
Sent: Thursday, May 09, 2019 10:22 AM
To: 'larryhodges@meycorp.com' <larryhodges@meycorp.com>
Cc: Johnson, Marion <Johnson.Marion@epa.gov>; Doherty, Michael <Doherty.Michael@epa.gov>; Niman, Aaron <niman.aaron@epa.gov>
Subject: FW: Changes to compounds to be evaluated in JMPR September 2019 [SEC=UNCLASSIFIED]

Dear Dr. Hodges,

Thank you for your email below.

I have cc'd Marion Johnson in our Registration Division who I understand handles this chemical. You should likely be communicating with Marion on this issue as far as it relates to EPA matters or any meetings you might request with the Agency.

I took the liberty of also cc'ing Dr. Michael Doherty who is on JMPR and is knowledgeable in this area as well as Aaron Niman who interfaces with Dr. Reichstein on US chemicals scheduling with respect to CCPR.

We would be happy to meet with you regarding "what data are required and how this data will be submitted to the CCPR", but this should be arranged through Marion Johnson.

David.

David J. Miller CAPT | USPHS
Chief, Chemistry & Exposure Branch
and Acting Chief, Toxicology & Epidemiology Branch
Health Effects Division
Office of Pesticide Programs
703-305-5352 (voice)
703-305-5147 (fax)

Visit www.epa.gov/pesticides

From: Larry Hodges <larryhodges@meycorp.com>
Sent: Wednesday, May 08, 2019 11:18 AM
To: Miller, David <Miller.DavidJ@epa.gov>
Subject: RE: Changes to compounds to be evaluated in JMPR September 2019 [SEC=UNCLASSIFIED]

Dear Mr. Miller,

The email response from Mr. Ian Reichstein indicates that aldicarb is scheduled for CCPR review in 2020. It is my understanding that supporting residue and toxicology studies must be submitted by November 1, 2019. Would it be possible to schedule a meeting to discuss compliance with CCPR data submission? As a generic registrant, without access to the studies that support our US registration, we need to understand what data are required and how this data will be submitted to the CCPR.

Thanks for your help,
Larry Hodges, Ph.D.
Director of Regulatory Affairs
AgLogic Chemical LLC

Phone: 919-932-5800

From: Reichstein, Ian [mailto:Ian.Reichstein@agriculture.gov.au]
Sent: Tuesday, May 7, 2019 8:40 PM

To: Larry Hodges <larryhodges@meycorp.com>
Cc: MADSEN, Soren <madsens@who.int>; Yang, YongZhen (AGPM) <YongZhen.Yang@fao.org>; Niman, Aaron <niman.aaron@epa.gov>; Budd, Karina <Karina.Budd@agriculture.gov.au>; Brisco, Gracia (AGFC) <Gracia.Brisco@fao.org>; Codex Contact Point <Codex.Contact@agriculture.gov.au>; Black, Tom <Tom.Black@agriculture.gov.au>; Garwood, Jenna <Jenna.Garwood@agriculture.gov.au>; Miller, David <Miller.DavidJ@epa.gov>; wibke.meyer@croplife.org
Subject: RE: Changes to compounds to be evaluated in JMPR September 2019 [SEC=UNCLASSIFIED]

Dear Larry

To be absolutely clear, as Chair of the CCPR eWG on Priorities, I have neither the power nor authority to change the status of a nomination in the CCPR Schedules and Priority Lists without first consulting with respective nominators.
Accordingly my email of 6 May was circulated to vested interests in the 2020 Schedule of JMPR Evaluations.

I have received a response from Codex Secretariat which correctly refers to the Codex Procedural Manual and a 2020 JMPR Schedule of Evaluations confirmed at the 51st session of CCPR.
I believe the only way forward is to proceed with the 2020 Schedule as agreed at CCPR51 and note the addition of terbufos and carbaryl as carryovers from the 2019 Schedule.

At the September / October 2019 JMPR data call-in, nominators to the 2020 Schedule will be required to respond with respective data submissions.
JMPR will prioritise terbufos and carbaryl higher and do its best to attend to all of the compounds nominated in the 2020 Schedule. Given the available evaluator resources, it is unlikely all compounds will be evaluated in 2020.

Therefore it will be critically important for each nominator to respond to the JMPR data call-in promptly and correctly.

In regard to your concerns for the aldicarb data package, I suggest that between now and October 2019, you continue to engage with the USEPA and JMPR Secretariats to determine a way forward.

I hope this clarifies and assists.

Kind regards
Ian

Ian Reichstein
Director - National Residue Survey
Residues & Food | Exports Division
Department of Agriculture and Water Resources

Position number: 13107
Phone +61 (0) 2 6272 5668
Mobile Ex. 6 Personal Privacy (PP)
Location: M9.185 Marcus Clarke Building
18 Marcus Clarke Street CANBERRA ACT 2601 Australia
PO Box 858 CANBERRA ACT 2601 Australia

From: Larry Hodges [mailto:larryhodges@meycorp.com]
Sent: Tuesday, 7 May 2019 11:21 PM
To: Reichstein, Ian <Ian.Reichstein@agriculture.gov.au>
Cc: MADSEN, Soren <madsens@who.int>; Yang, YongZhen (AGPM) <YongZhen.Yang@fao.org>; Niman, Aaron <niman.aaron@epa.gov>; Budd, Karina <Karina.Budd@agriculture.gov.au>; Brisco, Gracia (AGFC) <Gracia.Brisco@fao.org>; Codex Contact Point <Codex.Contact@agriculture.gov.au>; Black, Tom <Tom.Black@agriculture.gov.au>; Garwood, Jenna <Jenna.Garwood@agriculture.gov.au>
Subject: RE: Changes to compounds to be evaluated in JMPR September 2019 [SEC=UNCLASSIFIED]

Dear Mr. Reichstein,

I appreciate your email and information about aldicarb but I do not understand its current status. In your email of October 24, 2018 you said that aldicarb will be placed as a confirmed listing for the 2020 Schedule and in your email immediately below you indicate that aldicarb may be reclassified as RESERVE.

In my emails to you of February 26, 2019 and April 15, 2019 I explained that AgLogic Chemical LLC is a generic registrant and we do not have access to the toxicology and residue studies that have been submitted to the US EPA in support of aldicarb. Although AgLogic Chemical has met the statutory requirements that allow the US EPA to rely all aldicarb data that have been submitted in support of registration we are not allowed to have copies of the actual studies. Therefore, we are not able to submit these studies to the CCPR and WHO for review.

In my emails I noted three possible alternatives for providing data for the 2020 aldicarb review:

1. The US EPA recently completed and published its registration review for aldicarb. This document reviews and discusses all data required to support aldicarb registration in the USA. We could submit this document in place of the studies.
2. Since the US EPA already has all of the supporting studies, the aldicarb reviews could be written by the US EPA's residue and toxicology experts that participate in the CCPR and WHO.
3. The US EPA could provide the required studies to the CCPR and WHO for review by someone not from the US EPA.

Please let me know if aldicarb will remain on the 2020 schedule or if it will be reclassified as RESERVE. If aldicarb remains on the 2020 schedule how should the data be provided? If aldicarb is reclassified as RESERVE please let me know what this means as I am not familiar with the term.

Thanks and Best Regards,
Larry Hodges, Ph.D.
Director of Regulatory Affairs
AgLogic Chemical LLC

Phone: 919-932-5800

From: Reichstein, Ian [mailto:Ian.Reichstein@agriculture.gov.au]
Sent: Monday, May 6, 2019 7:18 PM
To: wibke.meyer@croplife.org; Dunlop Craig CHBS <craig.dunlop@syngenta.com>; Peter Chalmers <Peter.Chalmers@adama.com>; Larry Hodges <larryhodges@meycorp.com>; Michael Kaethner <michael.kaethner@bayer.com>; monika.a.richter@basf.com; Jane M Stewart <jane.stewart@basf.com>

Cc: MADSEN, Soren <madsens@who.int>; Yang, YongZhen (AGPM) <YongZhen.Yang@fao.org>; Niman, Aaron <niman.aaron@epa.gov>; Budd, Karina <Karina.Budd@agriculture.gov.au>; Brisco, Gracia (AGFC) <Gracia.Brisco@fao.org>; Codex Contact Point <Codex.Contact@agriculture.gov.au>; Black, Tom <Tom.Black@agriculture.gov.au>; Garwood, Jenna <Jenna.Garwood@agriculture.gov.au>
Subject: FW: Changes to compounds to be evaluated in JMPR September 2019 [SEC=UNCLASSIFIED]

Dear colleagues

Please note the email from our WHO representative Soren Madsen in regard to the JMPR periodic review of terbufos and carbaryl.
Both compounds are currently listed in the 2019 periodic review schedule.

For the reasons noted below, both compounds need to be moved to the 2020 JMPR Schedule of Periodic Reviews.
As the quota of periodic reviews is six compounds, two compounds in the current 2020 Schedule need to be reclassified as RESERVE.

For reference, the compounds in question are listed in the tables at the bottom of this message.

Two of the following compounds: aldicarb, metalaxyl / metalaxyl-M, diazinon, fipronil, prochloraz and methidathion need to be reclassified as RESERVE.
Please note that should evaluator resources become available, some of the reserves may be evaluated in 2020.

Noting the issues in regard Metalaxyl-M and proposed MRLs held at Step 7 for 15 years, I strongly recommend this compound and metalaxyl are not reclassified to RESERVE.

Please provide your thoughts / preferences within 5 working days?

Kind regards

Ian

IC Reichstein

Ian Reichstein
Director - National Residue Survey
Residues & Food | Exports Division
Department of Agriculture and Water Resources

Position number: 13107
Phone +61 (0) 2 6272 5668
Mobile + Ex. 6 Personal Privacy (PP)
Location: M9.185 Marcus Clarke Building
18 Marcus Clarke Street CANBERRA ACT 2601 Australia
PO Box 858 CANBERRA ACT 2601 Australia

From: MADSEN, Soren [mailto:madsens@who.int]
Sent: Thursday, 2 May 2019 6:08 PM
To: Reichstein, Ian <Ian.Reichstein@agriculture.gov.au>; Budd, Karina <Karina.Budd@agriculture.gov.au>
Cc: HO, Ngai Yin <hon@who.int>; LUNE, Nora <lunen@who.int>; Yang, YongZhen (AGPM)

<YongZhen.Yang@fao.org>
Subject: Changes to compounds to be evaluated in JMPR September 2019 [SEC=UNCLASSIFIED]

Dear Ian and Karina,

It was a pleasure meeting you in Macau.
I wish to inform you that we have had to make some changes in the JMPR schedule for the evaluation of Terbufos and Carbaryl.
Despite several attempts, it has not been possible to find willing and able epidemiological expertise to commit to the evaluation of these two compounds for the September 2019 JMPR meeting.
As time is drawing near, I have had to choose between an evaluation without the epidemiological component or a postponement of the evaluation to September 2020. We now have a senior epidemiologist who have committed to undertake the 2020 epidemiological evaluation, and I have decided to go for a complete (but postponed) evaluation rather than a less complete evaluation in accordance with the initial schedule for the September 2019 JMPR meeting.
I suppose that you may want to reflect these changes in the CCPR spreadsheet.

Best Regards,

Soren Madsen
Department of Food Safety and Zoonoses
World Health Organization
20, Avenue Appia, CH-1211 Geneva 27
Switzerland
Tel direct: + 41 22 791 36 97

++
++
++++++++++++++++++++++++++

RELEVANT TABLES FROM THE CCPR PRIORITY LISTS AND SCHEDULES – CURRENT 23 APRIL 2019

YEAR	TOXICOLOGY	RESIDUE	COMMODITIES	PREVIOUS EVALUATION	ADI	ARfD	MEMBER / MANUFACTURER	Comments
2019	carbaryl (008)			2001T, 2002R	0.008 (2001)	0.2 (2001)	Bayer CropScience	toxicological review only
2019	terbufos (167)			2003T, 2005R	0.0006 (1989)	0.002 (2003)	AMVAC	toxicological review only

YEAR	TOXICOLOGY	RESIDUE	MEMBER / MANUFACTURER	COMMODITIES	COMMENTS
2020	Aldicarb (117)	Aldicarb (117)	AgLogic Chemical LLC		Awaiting further advice on commodities from spo

2020	Metalaxyl-M (212) Metalaxyl (138)	Metalaxyl-M (212) Metalaxyl (138)	Syngenta / Australia		Toxicology and animal metabolism data only
2020	Diazinon (22) Note: Diazinon was scheduled for toxicological and residue assessment by an interim JMPR to be held in Spring 2016, based on concerns raised by IARC on the possible carcinogenic properties of the substance (see Summary Report JMPR2015).	Diazinon (22)	Adama	Pineapple, apple, pears, cherries, wheat, barley, onion, tomato, cabbage, chili and potatoes.	Falls under the 15-year rule (listed in Table 2B), la evaluation in 1996. EU Concerns are as follows: T substance is not authorised in the EU. The EU-AD 0.0002 mg/kg bw/day) is much lower than the JM (0.005 mg/kg bw/day). Using the existing CXLs an ARfD/ADI in the EFSA PRIMo model, serious publ concerns are identified after long-term dietary ex of diazinon. An acute dietary risk assessment was performed using CXLs. When using the JMPR IEST the JMPR-ARfD is not exceeded. By using the EFS model and the CXLs, the EU-ARfD is exceeded (IE case of scarole (175%), plums (132%), carrots (12 melons (121%), apples (118%), broccoli (117%), t (116%), pears (105%), head cabbage (105%), bov (102%). Refinement (IESTI 2) of the variability fac would still lead to exceedances of the ARfD for sc melons, plums and bovine meat (102-175%). Use HR would lower the short term exposure by a fac which would not result in an exceedance of ARfD without including the LOQs for the crops without the highest calculated TMDI values in % (EU) ADI 4990% in various populations (child, toddlers, ge public) and countries, with meats, pome fruit, ca sugar beets contributing the most (all >>100 % of ADI). It is acknowledged that the use of the STMR lower the long-term dietary exposure by approxi factor of 4-5, but this would still lead to an excee the ADI.
2020	Fipronil (202)	Fipronil (202)	BASF		006 Assorted tropical and sub-tropical fruits – ine Peel; 006 Assorted tropical and sub-tropical fruits inedible Peel; 006 Assorted tropical and sub-trop – inedible Peel; 006 Assorted tropical and sub-tro fruits – inedible Peel; 015 Pulses; 016 Root and tu vegetables; 020 Cereal grains; 021 Grasses for su syrup production; 04 Nuts and seeds; 023 Oilseed
2020	Prochloraz (142)	Prochloraz (142)	BASF / FMC / ADAMA		Last reviewed by JMPR in 2001. In 2011, Prochlor re-evaluated in the EU and a lower acute toxicolo endpoint of 0.025 mg/kg/bw/d was established c to a value of 0.1 set by JMPR in 2001. From the JM report (2004) the IESTI was calculated to be great 25% of the ARfD at 0.1 for several commodities. V lowering of the ARfD by a factor of 4, the CXLs fo edible offal (mammalian), grapefruit, mandarin, c papaya, pineapple, shaddocks/pomelos are expe be of concern. The EU values were derived from that do not appear to have featured in the JMPR evaluation. The multi-generation rat study "Read submitted as part of a dossier by a notifier and a dog study " Lancaster 1979" submitted by anothe notifier. In addition a change in the interpretatio significance of extended gestation in both the "C 1980 study" and the "Reader 1993" study also im It should also be noted the many papers reviewe of the literature search around prochloraz were a

					considered when the list of endpoints and critica were set.
2020	Methidathion (51)	Methidathion (51)		Peach, mango, apple, pear, cherry, mandarin, tea	Manufacturer support from Zenno Chem for mar peach scheduled for 2020¶If no support for exist then revocation of CXLs at CCPR49. - The active s has been re-evaluated for residues (after its first in 1972) in 1992. An ARfD was derived in the toxi re-evaluation in 1997.¶As a consequence of this couple of MRLs are not safe for consumers. Due t fact that no periodic re-evaluation of residues toc in 42 years it is proposed to carry out a new evalu The JMPR has established an ADI of 0.001 mg/kg and an ARfD of 0.01 mg/kg bw/d in 1997. A risk assessment was performed using the EFSA PRIMo including all MRLs that were considered relevant international trade. The ADI was exceeded for 25 European diets with the highest exposure repres 2392% of the ADI. Citrus fruits, olives for oil prod and milk were shown to be the main contributors fruits also exceeded the ARfD (up to 6631%). A se exposure calculation delete the existing MRLs for fruits, pome fruits and sunflower seeds still show that the ADI for 5 European diets was exceeded (301%). For further details see EFSA evaluation on internet at http://www.efsa.europa.eu/en/efsajournal/doc/
RESERVE	Quintozene (64)	Quintozene (64)	Crompton–AMVAC		Falls under the 15-year rule (listed in Table 2B), la evaluation in 1995. The EU proposes submit a co form on the basis of public health concerns. Quin containing more than 0.1% hexachlorobenzene is in the EU. For quintozene (containing less than 0. hexachlorobenzene), the necessity for deriving a has not been assessed (EU or JMPR). Using the C JMPR IESTI model and the ADI as surrogate ARfD, exceedance of the ARfD is found for ginger root (no exceedance is found for the EFSA PRIMo mod the (temporary) ADI of 0.01 mg/kg bw/day, the T the long-term dietary risk assessment does not e the ADI using the Codex MRLs and the EFSA PRIM However, there are many uncertainties regarding metabolites that can be formed, depending on ap of the active substance at growth stage and on ty

					plant. There is a lack of sufficient data to exclude consumer risks.
RESERVE	Ethoxyquin (35)	Ethoxyquin (35)			ONE CXL - PEAR The substance is not authorised and no import tolerances exist. EFSA concluded t metabolism data used by JMPR for establishing th residue definition for enforcement and risk asses could not be confirmed as the metabolism data s deficiencies using the JMPR residue definition. EF concluded that the CXL for pears exceeded the AI (109%) and proposed to lower the EU MRL to the The last periodic review of residues was performe JMPR in 1999 and of toxicology in 1998. This is approximately 15 years ago. It seems that Japan h recently performed a toxicological evaluation of t substance. / COMMENT: a toxicological review oc in 2005 – reviewed ADI and set ARfD

------ IMPORTANT - This email and any attachments have been issued by the Australian Government Department of Agriculture and Water Resources. The material transmitted is for the use of the intended recipient only and may contain confidential, legally privileged, copyright or personal information. You should not copy, use or disclose it without authorisation from the Department. It is your responsibility to check any attachments for viruses and defects before opening or forwarding them. If you are not an intended recipient, please contact the sender of this email at once by return email and then delete both messages. Unintended recipients must not copy, use, disclose, rely on or publish this email or attachments. The Department of Agriculture and Water Resources is not liable for any loss or damage resulting from unauthorised use or dissemination of, or any reliance on, this email or attachments. If you have received this e-mail as part of a valid mailing list and no longer want to receive a message such as this one, advise the sender by return e-mail accordingly. This notice should not be deleted or altered ------